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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/578,197

06/13/2006

Steven Reid

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EXAMINER

GUZO, DAVID

ART UNIT

PAPER NUMBER

1636

MAIL DATE

DELIVERY MODE

03/11/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/578,197	Applicant(s) REID ET AL.	
	Examiner David Guzo	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5,7,8,11 and 12 is/are rejected.
- 7) ☒ Claim(s) 1-4,6,9 and 10 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/20/06</u> . | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

35 USC 101 Rejections

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 12 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Applicants claim a baculovirus product produced by the method of claim 1. The method of claim 1 can produce any naturally occurring baculovirus and since the claimed baculovirus product is not recited as isolated or in some fashion different from the naturally occurring baculovirus, the claim reads on a product of nature.

35 USC 102 Rejections

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 12 is rejected under 35 U.S.C. 102(b) as being anticipated by Volkman et al.

Applicants claim a Baculovirus product produced by inoculating caterpillar larvae with a baculovirus inoculum; incubating inoculated caterpillar larvae; harvesting baculovirus occlusion bodies from the infected caterpillar larvae; extracting occlusion

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derived virus from the occlusion bodies; inoculating a culture of host insect cells with an inoculum of occlusion derived virus; incubating virus/cell culture; and harvesting baculovirus from the incubated virus/cell culture. The claim reads on any baculovirus or part thereof produced by the claimed method and hence the claim is a product-by-process claim.

Volkman et al. (J. Virol., 1976, Vol. 19, No. 3, pp. 820-832, see whole article, particularly p. 822) teaches purified compositions of occluded and non-occluded baculoviruses (AcMNPV). Absent evidence to the contrary, the baculovirus isolated by the methods of Volkman et al. is indistinguishable from the baculovirus made by the claimed method. It is noted that the patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process (See MPEP 2113).

35 USC 112, 2nd Paragraph Rejections

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 7, 8 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 is vague in the recitation of producing a “suitable amount of occlusion bodies working stock”. It is unclear what a “suitable amount” of occlusion bodies encompasses, i.e. suitable for what purpose?

Claim 7 is vague in that there is no antecedent basis for the terms “an occlusion bodies working stock” and “an occlusion bodies master stock” in Claim 1.

Claim 8 is vague in the recitation of the term “a relatively high MOI”. The term “relatively high” in claim 8 is a relative term which renders the claim indefinite. The term “relatively high” is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 11 is vague in that there is no antecedent basis for the term “the VPM3 media”.

Miscellaneous

Claims 1-12 are objected to because of the following informalities: Applicants, in some claims use the terms “Baculovirus” and “baculovirus” interchangeably and it is unclear if the capitalized term is different from the non-capitalized term. Applicants are encouraged to use uniform terminology throughout the claims. Appropriate correction is required.

The instant claims 1-11 are free of the art because the occluded virus is not the infectious baculovirus in *in vitro* cell cultures and baculovirus derived from occlusion

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bodies is virtually non-infectious *in vitro* (See Volkman et al., cited above). The skilled artisan would not have been motivated to use baculoviruses derived from occlusion bodies as the infectious virus for generating large quantities of baculovirus in cell cultures *in vitro*.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D., can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

February 22, 2008

/David Guzo/
Primary Examiner
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